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Reply to Office Action dated 03/09/2005

Application No. 10/001,357

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims**

1. (Currently amended) A computing device in communication with an implantable drug delivery device for delivering at least one drug to a patient, the drug delivery device having a reservoir containing at least one drug and a nonconformance monitor module configured to monitor at least one performance parameter, the computing device comprising an external acquisition device, the external acquisition device comprising in combination:

- (a) a memory having stored therein pump performance acquisition instructions;
- (b) a telemetry module providing bi-directional communication between the external acquisition computing device and the implantable drug delivery device and providing the pump performance acquisition instructions to the implantable drug delivery device and receiving pump performance data from the implantable drug delivery device; and
- (c) a nonconformance management module contained within the memory receiving the pump performance data and determining whether the pump is conforming to performance requirements, and determining what action should be taken if non-conformance is determined.

2. (Currently amended) ~~The computing device of claim 1,~~ A computing device in communication with an implantable drug delivery device for delivering at least one drug to a patient, the drug delivery device having a reservoir containing at least one drug and a nonconformance monitor module configured to monitor at least one performance parameter, the computing device comprising in combination:

- (a) a memory having stored therein pump performance acquisition instructions;
- (b) a telemetry module providing bi-directional communication between the computing device and the implantable drug delivery device and providing the pump performance acquisition instructions to the implantable drug delivery device and receiving pump performance data from the implantable drug delivery device, wherein the pump performance data is selected from the group consisting of pump reservoir pressure, fluid outlet pressure, propellant pressure, fluid flow rate, battery current drain, motor current drain, motor drive current profile, battery voltage, and physiologic sensor output level; and

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(c) a nonconformance management module contained within the memory receiving the pump performance data and determining whether the pump s conforming to performance requirements, and determining what action should be taken if non-conformance is determined.

3. (Currently amended) The computing device of claim 24, wherein the memory includes patient performance requirements information.

4. (Currently amended) The computing device of claim 24, wherein the memory includes pump manufacturer requirements information.

5. (Currently amended) The computing device of claim 24, wherein the memory includes a scheduling module for scheduling an appointment to service the device.

6. (Original) The computing device of claim 5, wherein the scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient.

7. (Original) The computing device of claim 6, wherein the computing device is operatively coupled to the entity via a computing network.

8. (Original) The computing device of claim 7, wherein the computing network is an Internet.

9. (Withdrawn) A system for providing treatment therapy to a patient comprising in combination:

- (a) an implantable drug delivery device comprising:
  - (i) a housing;
  - (ii) at least one drug reservoir within the housing and each configured to contain at least one drug;
  - (iii) a flow control module controlling the flow of drug; from the drug reservoir through an infusion port;
  - (iv) electronics coupled to the flow control for adjusting the flow of drug by the flow control module;

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(v) a telemetry module coupled to the electronics for providing bi-directional communication between the delivery device and an external programmer; and

(vi) a nonconformance monitor module coupled to the electronics, the drug monitor configured to monitor at least one pump performance parameter and generating pump performance data; and

(b) an external programmer comprising

(i) a telemetry module providing bi-directional communication between the external programmer and the implantable drug delivery device. and

(ii) a nonconformance management module stored in the second memory for determining whether the pump is conforming to performance requirements, based upon the pump performance data from the drug monitor module, and determining what action should be taken if non-conformance is determined.

10. (Withdrawn) The system of claim 9, further comprising:

(c) at least one entity selected from the group consisting of an insurance provider, a pharmacy, a hospital, a caregiver, a physician, and a device manufacturer; and

(d) a computing network coupling the external programmer to the entity.

11. (Withdrawn) The system of claim 9, wherein the pump performance data is selected from the group consisting of pump reservoir pressure, fluid outlet pressure, propellant pressure, fluid flow rate, battery current drain, motor current drain, motor drive current profile, battery voltage, and physiologic sensor output level.

12. (Previously presented) An implantable drug delivery device having performance data reporting capability comprising in combination:

(a) a memory having stored therein pump performance acquisition instructions;

(b) at least one nonconformance monitor module for monitoring at least one pump operation variable in accordance with the pump performance acquisition instructions to produce pump performance data;

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(c) a non-conformance management module receiving the pump performance data, determining whether the pump is conforming to performance requirements, and determining what action should be taken if non-conformance is determined; and

(d) a telemetry module that receives the performance acquisition instructions, the performance acquisition instructions being stored in the memory.

13. (Previously presented) An implantable drug delivery device having performance data reporting capability comprising in combination:

(a) a memory having stored therein pump performance acquisition instructions;

(b) at least one nonconformance monitor module for monitoring at least one pump operation variable in accordance with the pump performance acquisition instructions to produce pump performance data, wherein the pump operation variable is selected from the group consisting of pump reservoir pressure, fluid outlet pressure, propellant pressure, fluid flow rate, battery current drain, motor current drain, motor drive current profile, battery voltage, and physiologic sensor output level; and

(c) a non-conformance management module receiving the pump performance data, determining whether the pump is conforming to performance requirements, and determining what action should be taken if non-conformance is determined.

14. (Previously presented) An implantable drug delivery device having performance data reporting capability comprising in combination:

(a) a memory having stored therein pump performance acquisition instructions;

(b) at least one nonconformance monitor module for monitoring at least one pump operation variable in accordance with the pump performance acquisition instructions to produce pump performance data, wherein the pump performance data is selected from the group consisting of pump reservoir pressure, fluid outlet pressure, propellant pressure, fluid flow rate, battery current drain, motor current drain, motor drive current profile, battery voltage, and physiologic sensor output level; and

(c) a non-conformance management module receiving the pump performance data, determining whether the pump is conforming to performance requirements, and determining what action should be taken if non-conformance is determined.

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15. (Previously presented) The implantable drug delivery device of claim 12, further comprising:

(e) at least one reporting module to report the pump performance data via telemetry to an external device.

16. (Previously presented) The implantable drug delivery device of claim 12, wherein the memory has stored therein patient performance requirements information that is also received by the non-conformance management module.

17. (Previously presented) An implantable drug delivery device having performance data reporting capability comprising in combination:

(a) a memory having stored therein pump performance acquisition instructions;  
(b) at least one nonconformance monitor module for monitoring at least one pump operation variable in accordance with the pump performance acquisition instructions to produce pump performance data; and

(c) a non-conformance management module receiving the pump performance data, determining whether the pump is conforming to performance requirements, and determining what action should be taken if non-conformance is determined, wherein the memory has stored therein pump manufacturer requirements information that is also received by the non-conformance management module.

18. (Previously presented) The implantable drug delivery device of claim 12, wherein the memory has stored therein pump telemetry data that is also received by the non-conformance management module.

19. (Withdrawn) An implantable drug delivery device having performance data reporting capability comprising in combination:

(a) a housing;  
(b) a drug reservoir carried in the housing configured to contain at least one drug;  
(c) a flow control module coupled to the drug reservoir for controlling the flow of the drug from the drug reservoir through an infusion port;  
(d) electronics coupled to the flow control and a power source;

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- (e) a telemetry module coupled to the electronics;
- (f) a memory coupled to the electronics, the memory containing pump performance acquisition instructions;
- (g) at least one monitoring module coupled to the memory and the electronics that monitors at least one pump operation variable according to the pump performance acquisition instructions to produce performance data;
- (h) a non-conformance management module receiving the pump performance data, determining whether the pump is conforming to performance requirements, and determining what action should be taken if non-conformance is determined; and
- (i) at least one reporting module coupled to the memory and the electronic, the reporting module configured to activate the telemetry module to report performance data.

20. (Withdrawn) A non-conformance management module for determining whether an implantable device is operating as configured comprising in combination:

- (c) a first interface for receiving pump performance data from a drug monitor module;
- (d) a second interface for receiving pump performance acquisition instructions, patient performance requirements, pump manufacturer requirements, and pump telemetry data from a memory;
- (e) a non-conformance management algorithm for determining whether the implanted device is performing as configured based upon the pump performance data and at least one of the pump performance acquisition instructions, patient performance requirements, pump manufacturer requirements, and pump telemetry data.

21. (Withdrawn) A method for reporting implantable drug delivery device performance data, comprising:

- (a) establishing pump performance acquisition instructions;
- (b) operating the pump;
- (c) monitoring pump variables according to the pump performance acquisition instructions;
- (d) recording pump performance data; and

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- (e) reporting the pump performance data from the implantable drug delivery device to an external device via telemetry.
22. (Withdrawn) Computer executable instructions for performing the steps recited in claim 21.
23. (Withdrawn) A method for controlling an implantable drug delivery device to conform with performance requirements:
- (a) receiving pump diagnostic data regarding the pump;
  - (b) comparing the data with at least one parameter selected from the group consisting of pump performance acquisition instructions, patient performance requirements, pump manufacturer requirements, and pump telemetry data;
  - (c) determining whether the pump is conforming with performance requirements provided by the parameter; and
  - (d) if the pump is not in conformance, determining whether to reprogram the pump or to require a non-programming change.
24. (Withdrawn) Computer executable instructions for performing the steps recited in claim 23.
25. (Withdrawn) The method for controlling an implantable drug delivery device of claim 23, further comprising the step of:
- (e) if the pump is to be reprogrammed, altering at least one pump parameter.
26. (Withdrawn) The method for controlling an implantable drug delivery device of claim 23, further comprising the step of:
- (e) if the pump is to require a non-programming change, performing at least one non-programming change to the pump.
27. (Withdrawn) The method for controlling an implantable drug delivery device of claim 23, further comprising the step of:
- (e) storing an event to a database reflective of the determination steps.

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28. (Withdrawn) The method for controlling an implantable drug delivery device of claim 23, further comprising the step of:

(e) reporting the pump performance data from the implantable drug delivery device to an external device via telemetry.

29. (Previously presented) The implantable drug delivery device of claim 14, wherein the non-conformance management module further determines whether the pump performance data is indicative of a non-programming change to the implantable drug delivery device.

30. (Previously presented) The implantable drug delivery device of claim 29, wherein the non-conformance management module further performs the non-programming change to the implantable drug delivery device.

31. (Previously presented) The implantable drug delivery device of claim 14, wherein the non-conformance management module further determines whether the pump performance data is indicative of a programming change to the implantable drug delivery device.

32. (Previously presented) The implantable drug delivery device of claim 31, wherein the non-conformance management module further performs the programming change to the implantable drug delivery device.

33. (Previously presented) The computing device of claim 2, wherein the nonconformance management module further determines whether the pump performance data is indicative of a non-programming change to the pump.

34. (Previously presented) The computing device of claim 33, wherein the nonconformance management module further performs the non-programming change to the pump.

35. (Previously presented) The computing device of claim 2, wherein the nonconformance management module further determines whether the pump performance data is indicative of a programming change to the pump.

36. (Previously presented) The computing device of claim 35, wherein the nonconformance management module further performs the programming change to the pump.



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37. (Previously presented) The computing device of claim 3<sup>4</sup>, wherein the nonconformance management module reports the pump performance data to an external device through the telemetry module.

38. (Previously presented) The computing device of claim 2, further comprising:  
a storage device that receives an event indication that is associated with the pump performance data.

39. (Previously presented) The implantable drug delivery device of claim 14, further comprising:

(d) at least one reporting module to report the pump performance data via telemetry to an external device.

40. (Previously presented) The implantable drug delivery device of claim 14, wherein the memory has stored therein patient performance requirements information that is also received by the non-conformance management module.

41. (Previously presented) The implantable drug delivery device of claim 14, wherein the memory has stored therein pump telemetry data that is also received by the non-conformance management module.

42. (Previously presented) The implantable drug delivery device of claim 13, further comprising:

(d) at least one reporting module to report the pump performance data via telemetry to an external device.

43. (Previously presented) The implantable drug delivery device of claim 13, wherein the memory has stored therein patient performance requirements information that is also received by the non-conformance management module.

44. (Previously presented) The implantable drug delivery device of claim 13, wherein the memory has stored therein pump telemetry data that is also received by the non-conformance management module.

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45. (Previously presented) The implantable drug delivery device of claim 14, further comprising:

(d) at least one reporting module to report the pump performance data via telemetry to an external device.

46. (Previously presented) The implantable drug delivery device of claim 17, wherein the memory has stored therein patient performance requirements information that is also received by the non-conformance management module.

47. (Previously presented) The implantable drug delivery device of claim 14, wherein the memory has stored therein pump telemetry data that is also received by the non-conformance management module.

48. (New) A computing device in communication with an implantable drug delivery device for delivering at least one drug to a patient, the drug delivery device having a reservoir containing at least one drug and a nonconformance monitor module configured to monitor at least one performance parameter, the computing device comprising an external acquisition device, the external acquisition device comprising in combination:

(a) a memory having stored therein pump performance acquisition instructions and pump manufacturer requirements information;

(b) a telemetry module providing bi-directional communication between the external acquisition computing device and the implantable drug delivery device and providing the pump performance acquisition instructions to the implantable drug delivery device and receiving pump performance data from the implantable drug delivery device; and

(c) a nonconformance management module contained within the memory receiving the pump performance data and determining whether the pump is conforming to performance requirements, and determining what action should be taken if non-conformance is determined.

49. (New) A computing device in communication with an implantable drug delivery device for delivering at least one drug to a patient, the drug delivery device having a reservoir

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containing at least one drug and a nonconformance monitor module configured to monitor at least one performance parameter, the computing device comprising an external acquisition device, the external acquisition device comprising in combination:

(a) a memory having stored therein pump performance acquisition instructions and a scheduling module for scheduling an appointment to service the device;

(b) a telemetry module providing bi-directional communication between the external acquisition device and the implantable drug delivery device and providing the pump performance acquisition instructions to the implantable drug delivery device and receiving pump performance data from the implantable drug delivery device; and

(c) a nonconformance management module contained within the memory receiving the pump performance data and determining whether the pump is conforming to performance requirements, and determining what action should be taken if non-conformance is determined.